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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,545	01/12/2004	David Phillips	048501/273281	1302

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,545	PHILLIPS ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 13, 21 and 22 are drawn to a pharmaceutical composition comprising follistatin, classified in class 514, subclass 12, for example.

II. Claims 1, 8, 9, 13, 21, 22, 37 and 39 are drawn to a pharmaceutical composition comprising an antibody to activin A, classified in class 424, subclass 130.1, for example.

III. Claims 1, 8, 9, 13, 21, 22, 37 and 39 are drawn to a pharmaceutical composition comprising an antibody to activin AB, classified in class 424, subclass 130.1, for example.

IV. Claims 1, 8, 9, 13, 21, 22, 37 and 39 are drawn to a pharmaceutical composition comprising an antibody to activin B, classified in class 424, subclass 130.1, for example.

V. Claims 1, 8, 10-13, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody against a heterodimer or homodimer of mature inhibin β_A, classified in class 424, subclass 145.1, for example.

VI. Claims 1, 8, 10-13, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody against a heterodimer or homodimer of mature inhibin β_B, classified in class 424, subclass 145.1, for example.

VII. Claims 1, 13-15, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to ActRIIA, classified in class 424, subclass 143.1, for example.

VIII. Claims 1, 13-15, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to ActRIIB, classified in class 424, subclass 143.1, for example.

IX. Claims 1, 13-15, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to ActRIA, classified in class 424, subclass 143.1, for example.

X. Claims 1, 13-15, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to ActRIB, classified in class 424, subclass 143.1, for example.

XI. Claims 1, 13-15, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to ALK2, classified in class 424, subclass 143.1, for example.

XII. Claims 1, 13-15, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to ALK4, classified in class 424, subclass 143.1, for example.

XIII. Claims 1, 13, 16, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to a receptor for activin A, classified in class 424, subclass 143.1, for example.

XIV. Claims 1, 13, 16, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to a receptor for activin AB, classified in class 424, subclass 143.1, for example.

XV. Claims 1, 13, 16, 21 and 22 are drawn to a pharmaceutical composition comprising an antibody to a receptor for activin B, classified in class 424, subclass 143.1, for example.

XVI. Claims 1, 13, 17, 21 and 22 are drawn to a pharmaceutical composition comprising Smad6, classified in class 514, subclass 12, for example.

XVII. Claims 1, 13, 17, 21 and 22 are drawn to a pharmaceutical composition comprising Smad7, classified in class 514, subclass 12, for example.

XVIII. Claims 1, 13 and 18-22 are drawn to a pharmaceutical composition comprising a molecule that specifically inhibits TGFβ/activin type I receptors, classified in class 514, subclass 2, for example.

XIX. Claim 23 is drawn to a process for preparing the pharmaceutical composition, which comprises homogenously mixing at least one activin antagonist with a pharmaceutically acceptable carrier, adjuvant and/or diluent, classified in class 435, subclass 69.6, for example.

XX. Claims 24-29 are drawn to a method for the treatment of disease associated with fibrosis in a vertebrate, comprising administering a therapeutically effective amount of at least one activin antagonist, classified in class 424, subclass 141.1, for example.

XXI. Claims 30-36 are drawn to a method for screening for a disease associated with fibrosis in a vertebrate, comprising contacting a sample from the vertebrate with an antibody raised against an activin polypeptide and/or an antibody raised against a follistatin polypeptide, classified in class 435, subclass 7.2, for example.

XXII. Claims 38-41 are drawn to a diagnostic kit for the detection of a disease associated with fibrosis in a vertebrate, comprising an antibody to follistatin, classified in class 424, subclass 130.1, for example.

XXIII. Claims 42-49 are drawn to methods of gene therapy, classified in class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and each of II-XVIII and XXII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design because they are directed to pharmaceutical compositions and kits comprising different polypeptides and antibodies raised against molecules with divergent structures and divergent functions. While the peptides of Inventions I and XVI-XVIII and the antibodies of Inventions II-XV and XXII are polypeptides, they are structurally and functionally distinct molecules; any

relationship between a peptide and an antibody is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Furthermore, Inventions I-XVIII and XXII are distinct each one from the other, because they are drawn to unique peptides, as evidenced by their divergent structures.

Each structure recited by the claims must be searched separately and thus examining more than one peptide or polypeptide of Inventions I-XVIII and XXII together would impose a serious search burden. Even a polypeptide or peptide and an antibody that binds to the polypeptide or peptide require different searches. Antibodies that bind to an epitope of a peptide may be known even if a peptide is novel. In addition, the technical literature search for the peptides of are not coextensive, i.e., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XIX and each of XX, XXI and XXIII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function and effects. For example, the process of preparing a pharmaceutical of Invention XIX does not require the treatment steps of Inventions XX

or XXIII, nor does it require the screening steps of Invention XXI. Similarly, the method of screening of Invention XXI does not require the treatment steps of Inventions XX or XXIII. In addition, although both of Inventions XX and XXIII recite treatment steps, Invention XX requires treatment with a peptide antagonist, whereas Invention XXIII requires treatment with a nucleic acid molecule. Furthermore, all of these methods require different reagents, i.e., the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XIX and each of I-XVIII and XXII are related as process of making and product(s) made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to produce a plurality of activin antagonists that are not recited by the instant claims.

Inventions XX and each of I-XVIII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the peptides of inventions I-XVIII and XXII can be used in *in vivo* imaging techniques, for example.

Inventions XXI and each of I-XVIII and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the peptides of inventions I-XVIII, XXII and XXIII can be used in treatment methods, for example.

Inventions XXIII and each of I-XVIII and XXII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the methods of invention XXIII do not recite the use of or production of the compositions of inventions I-XVIII and XXII.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed Inventions I-XVIII, XX and XXI: diseases associated with fibrosis.

a. Hyperproliferative fibrotic disease

b. Inflammatory fibrotic disease

c. Pulmonary fibrosis

d. Inflammatory bowel disease

e. Ulcerative colitis

f. Crohn's disease

g. Liver fibrosis

h. Cirrhosis

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-22 and 24-36 are generic.

If Applicants select any one of Inventions I-XVIII, XX or XXI, one species from the fibrotic disease group must be chosen to be fully responsive.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicants traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Gregory S. Emch, Art Unit 1649.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
05 September 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER